Which policy for new psychoactive drugs?

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Which policy for New Psychoactive Drugs? A Commentary

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Summary statement

Psychoactive drugs have their specific profiles of potential harms and benefits. The increase of new drugs creates the need for procedures how to assess the profiles and to regulate availability and use according to profiles.

The paper by Reuter and Pardo (1) discusses the many aspects of how to deal with the rapidly increasing number of what is termed “new psychoactive substances” (NPS). This commentary focusses on one of the essential aspects: the harms to individuals and society.

The authors comment a total ban of NPS without considering the harms of a given substance as "normatively troubling". This invites to look in more detail at which harms are of relevance and how to assess those. British and Dutch experts developed models for risk and harm assessment (2, 3). A detailed analysis of drug harms is based on 16 criteria in 3 clusters (physical, psychological, social) of harm to users and harms to others. The result of this expert consultation process is a table of 20 legal and illegal drugs ranked according to harms, showing enormous differences (4). Another approach is to include user opinions besides experts to determine harms, resulting in a surprising coincidence between the two (5). And a recent model uses the margin of exposure approach MOE (ratio between medium lethal dose in animal experiments and estimated human intake) for determining the mortality risks of substances (6).

All these efforts document large differences of risks and harms attributable to known substances, and it is reasonable to presume that new substances will show similar differences. However, when they are new on the market, we do not have the data yet which allow an assessment. One strategy is to estimate the risks of a new substance on the basis of its chemical structure, while setting up a monitoring system for new drugs and collect the necessary data in a limited period of time, e.g. during 12 months (7). An ongoing monitoring system (collecting data from surveys, emergency rooms, treatment organizations, user organizations, toxicology e. a.) has the potential to adapt the harm profiles in the light of changing experiences and for informing consumer preferences and public health messages besides regulation strategies. A total ban is not only normatively troubling but also missing a chance for evidence-based guidance.

What are the alternatives to prohibition of substances with a given harm profile? A number of EU Member States regulate the availability of new

drugs under enforced consumer protection or medicines legislation, presenting a more flexible control system (8). So-called harm reduction measures are prominent in the case of legal substances, such as density and opening hours of alcohol outlets or smoke-free environments (9, 10). Such measures are in place to protect users and to prevent harm to others as well. Under a regime of tolerance for illegal substances, consumer safety is protected by qualitative and quantitative restrictions, e.g. for cannabis (coffee shop regulations, cannabis social clubs regulations). In states where cannabis prohibition is replaced by regulations in a licensing system, such restrictions (e.g. minimal age, marihuana quantities per month, number of cannabis plants, THC content, driving restrictions, product quality) are introduced and controlled (11, 12). An interim-licensing of NPS in New Zealand was repealed on the basis of reports of adverse effects. Pre-licensing assessment of substances was inadequate, and as a consequence the Ministry of Health prepared more appropriate requirements for product testing and further retail controls (13, 14). The urgent need for tackling the regulatory challenges is well recognized since years (15).

Another relevant issue is the balance of harm potential and potential benefits of a given substance. When discussing the option to use medicinal law, the Reuter/Pardo paper mentions a ruling of the European Court of Justice with its radical distinction of "intoxication" and "beneficial effects". which is problematic in the light of human experience. Controlled substances played a role as medicines in the past, from opiates to cocaine to cannabis. The dose makes the poison (Paracelsus). The rediscovery of beneficial effects of prohibited substances, starting with the prescription of Cannabis for defined indications, goes on for LSD (16) and Psylocibin (17). Others may follow. Are there more beneficial effects to be considered under medicinal law? Special cosmetics and nutritional products claim to improve our wellbeing and are sold in pharmacies. There may come a need to identify the relevant health benefits of NPS and the appropriate assessment procedures.

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